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# United States Patent [19]

## Bailey et al.

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[54]	COMPOSITIONS FOR HUMAN AND
	ANIMAL CONSUMPTION CONTAINING
	REDUCED FOLATES AND METHODS FOR
	MAKING AND USING SAME

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[52] **U.S. Cl.** ...... **426/72**; 426/549; 426/801; 426/807; 514/258; 544/261

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#### [56] References Cited

#### U.S. PATENT DOCUMENTS

1,431,525	10/1922	Hoffman .
2,052,219	8/1936	Dickens .
3,833,739	9/1974	Pedersen et al
4,753,926	6/1988	Lucas et al
4,834,987	5/1989	Lembke et al
5,006,655	4/1991	Müller et al
5,118,505	6/1992	Koltringer .
5,563,126	10/1996	Allen et al
5,624,686	4/1997	Shimoda et al

### FOREIGN PATENT DOCUMENTS

0 382 019 A1 8/1990 European Pat. Off. .

0 388 827 A1	9/1990	European Pat. Off
0 482 493 A2	4/1992	European Pat. Off
0 595 005 A1	5/1994	European Pat. Off
0 646 322 A1	4/1995	European Pat. Off
407147911A	6/1995	Japan .
407291864A	11/1995	Japan .
408070788A	3/1996	Japan .

#### OTHER PUBLICATIONS

IMSWorld database accession No. 94:61435 Druglaunch (1994).

Brown, J.P., et al., Gastroenterology 64(2):223–232 (1973). Colman, N., et al., Am J Clin Nutr 28:459–464 (1975). Gregory, J.F. et al., Am J Clin Nutr 55:1147–1153 (1992). O'Broin, J.D., et al., Am J Clin Nutr 28:438–444 (1975). Perry, J. and Chanarin, I., Br J Haemo 18:329–339 (1970). Tamura, T. and Stokstad, E.L.R., Br J. Haemo 25:513–532 (1973).

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#### [57] ABSTRACT

A composition for human or animal consumption for supplying folate which includes a natural isomer of reduced folate, such as (6S)-tetrahydrofolic acid, 5-methyl-(6S)tetrahydrofolic acid, 5-formyl-(6S)-tetrahydrofolic acid, 10-formyl-(6R)-tetrahydrofolic acid, 5,10-methylene-(6R)tetrahydrofolic acid, 5,10-methenyl-(6R)-tetrahydrofolic acid, 5-formimino-(6S)-tetrahydrofolic acid, and their polyglutamyl derivatives is disclosed. Such compositions include multivitamin preparations (with or without minerals and other nutrients); breakfast foods such as prepared cereals, toaster pastries and breakfast bars; infant formulas; dietary supplements and complete diet and weight-loss formulas and bars; animal feed (for example pet foods) and animal feed supplements (such as for poultry feed). The amount of the natural isomer of a reduced folate in a composition for human consumption can range between about 5% and about 200% of the daily requirement for folic acid per serving or dose.

### 44 Claims, No Drawings